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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/083,474 | 02/27/2002 | Irena Bronstein | 4085-252-27 CONT | 5776 |

7590 05/06/2004

PIPER MARBURY RUDNICK & WOLFE LLP
Supervisor, Patent Prosecution Services
1200 Nineteenth Street, N.W.
Washington, DC 20036-2412

| EXAMINER | |
|---|---|
| STRZELECKA, TERESA E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1637 | 4 |

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/083,474 | BRONSTEIN ET AL. | |
| | Examiner | Art Unit | |
| | Teresa E Strzelecka | 1637 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 7-9 is/are pending in the application.

4a) Of the above claim(s) 9 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 7 and 8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 7 and 8, drawn to a composition comprising oligonucleotides on a surface, the oligonucleotides provided with a chemiluminescent precursor, classified in class 536, subclass 24.3, for example.

   II. Claim 9, drawn to a method for detecting nucleic acid in a sample by contacting the nucleic acid with a composition of claim 7, classified in class 435, subclass 6, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of claim 9 can be used with an entirely different product, such as radioactively-labeled probes, rather than with the composition of claim 7.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Steven Kelber on October 14, 2003, a provisional election was made without traverse to prosecute the invention of Group I, claims 7 and 8. Affirmation of this election must be made by applicant in replying to this Office action. Claim 9 is

withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §

103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Claims 7 and 8 will be examined.

***Claim interpretation***

8. Before proceeding with claim rejections, interpretation of some of the claim terms will be provided.

A) Term "inspectible surface" is interpreted as any surface, since any surface can be inspected either directly or by optical equipment.

B) The limitation "oligonucleotide being provided with a chemiluminescent precursor" is interpreted as the presence of the chemiluminescent precursor in the composition containing the oligonucleotide. The precursor ay or may not be bound to the oligonucleotide.

C) The limitation "such that together they may be used for analysis of the sequence of a nucleic acid expressed by an organism" is an intended use of the composition, therefore it is not being taken into account when comparing properties of the claimed composition with prior art.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Dattagupta et al. (U.S. Patent No. 4,794,073).

Regarding claim 7, Dattagupta et al. teach a composition of matter comprising:

a support which comprises an inspectible surface (Dattagupta et al. teach supports for solid-phase hybridization formats, such as polymeric materials in the form of membranes, beads, microtiter plates, etc.; col. 9, lines 65-67; col. 11, lines 60-67; col. 12, lines 1-7 and 60-67; col. 13, lines 1-11);

a plurality of oligonucleotides provided on such surface, at least some of said oligonucleotides being provided with a chemiluminescent precursor, which precursor can be converted to a chemiluminescent moiety which can be triggered to luminescence (Dattagupta et al. teach nucleic acid probes immobilized on the solid support (col. 12, lines 46-60; col. 13, lines 12-55). The probes comprise a nucleic acid sequence and a chemiluminescent precursor linked to the nucleic acid sequence (col. 2, lines 12-17 and 27-39; col. 8, lines 4-32). The precursor can be

converted to a chemiluminescent mioiety by a reaction with an oxidant and a peroxidase (col. 9, lines 18-40 and 57-65).)

Regarding claim 8, Dattagupta et al. teach probes which are used for detection of nucleic acids by hybridization, the probes comprising different nucleotides (col. 10, lines 45-67; col. 14, lines 40-56).

11. Claims 7 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Ullman et al. (U.S. Patent No. 6,143,514 A).

Ullman et al. teach a composition of matter comprising:

a support which comprises an inspectible surface (Ullman et al. teach a matrix (=support) in the form of water-insoluble material (col. 14, lines 39-63), to which specific binding pair (sbp) members, such as polynucleotides, are bound (col. 14, lines 64-67; col. 20, lines 19-39);

a plurality of oligonucleotides provided on such surface, at least some of said oligonucleotides being provided with a chemiluminescent precursor, which precursor can be converted to a chemiluminescent moiety which can be triggered to luminescence (Ullman et al. teach a plurality of sbp members immobilized on the solid support (col. 15, lines 54-59). The sbp members are provided with a chemiluminescent precursor, which is also bound to the matrix (col. 4, lines 51-55; col. 15, lines 36-53). The chemiluminescent precursors are olefins (col. 4, lines 56-67; col. 5, lines 33-45) which can be converted to a chemiluminescent mioiety by a reaction with singlet oxygen (col. 5, lines 1-32; col. 6, lines 19-36).)

***Double Patenting***

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937,

214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 7 and 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,800,999 in view of Lipschutz et al. (Biotechniques, vol. 19, pp. 442-447, 1995).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claim 1 of the U.S. Patent No. 5,800,999 is drawn to a labeled biological probe, comprising: a first biological moiety selected from the group consisting of a nucleic acid, a peptide nucleic acid, a protein, a steroid and a carbohydrate, said biological moiety bearing a 1,2-dioxetane precursor bound thereto, such that, upon exposure to singlet oxygen, said precursor is converted to a 1,2-dioxetane moiety bound to said biological moiety which 1,2-dioxetane moiety subsequently decomposes to release light.

Claim 3 of the U.S. Patent No. 5,800,999 is drawn to A labeled probe, comprising: a first moiety selected from the group consisting of a nucleic acid, peptide nucleic acid, protein, steroid, carbohydrate, pharmaceutical drug, non-pharmaceutical drug, and a non-drug hapten, wherein said first moiety corresponds to a target component of a sample, said first moiety bearing bound to it a

1,2-dioxetane precursor moiety which, upon exposure to a suitable trigger, decomposes to release light.

The products of claims 1 and 3 differ from the composition in claims 7 and 8 in that they lack a support to which the probes are bound. Lipschutz et al. teach oligonucleotide probe arrays, which comprise oligonucleotide probes of different sequences bound to a solid support (page 443, paragraph 3; page 445, paragraph 1-3; page 446, paragraphs 4, 5). These oligonucleotide arrays are used to analyze sequences of nucleic acids of an organism, such as HIV, bacteria and humans (page 445, last paragraph; page 446paragraphs 1-3 and 7; page 447).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the nucleic acid probes of claims 1 and 3 of the U.S. Patent No. 5,800,999 arranged in the array of Lipschutz et al. The motivation to do so, provided by Lipschutz et al., would have been that arrays provided "a powerful tool for rapid investigations in sequence checkin, pathogen detection, expression monitoring and DNA molecular recognition" (Abstract).

14. Claims 7 and 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 6,451,531 in view of Lipschutz et al. (Biotechniques, vol. 19, pp. 442-447, 1995).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claim 1 of the U.S. Patent No. 6,451,531 is drawn to a labeled biological probe, comprising:

a first biological moiety selected from the group consisting of a nucleic acid, a peptide nucleic acid, a protein, a steroid and a carbohydrate, said biological moiety bearing a 1,2-dioxetane precursor bound thereto, such that, upon exposure to singlet oxygen, said precursor is converted to a 1,2-dioxetane moiety bound to said biological moiety which 1,2-dioxetane moiety subsequently decomposes to release light, wherein the 1,2-dioxetane moiety has the formula: (omitted), wherein T is a polycycloalkyl group, R is a substituted or unsubstituted alkyl, cycloalkyl or aryl group, Ar is an aryl moiety, X is an enzyme-cleavable group and Y is hydrogen or other electron donating or electron withdrawing group.

The product of claim 1 differs from the composition in claims 7 and 8 in that they lack a support to which the probes are bound. Lipschutz et al. teach oligonucleotide probe arrays, which comprise oligonucleotide probes of different sequences bound to a solid support (page 443, paragraph 3; page 445, paragraph 1-3; page 446, paragraphs 4, 5). These oligonucleotide arrays are used to analyze sequences of nucleic acids of an organism, such as HIV, bacteria and humans (page 445, last paragraph; page 446paragraphs 1-3 and 7; page 447).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the nucleic acid probes of claims 1 and 3 of the U.S. Patent No. 5,800,999 arranged in the array of Lipschutz et al. The motivation to do so, provided by Lipschutz et al., would have been that arrays provided "a powerful tool for rapid investigations in sequence checkin, pathogen detection, expression monitoring and DNA molecular recognition" (Abstract).

15. No claims are allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
October 21, 2003

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

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TS
October 21, 2003

JEFFREY FREDMAN
PRIMARY EXAMINER